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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/087,190

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EXAMINER

BLANCHARD, DAVID J

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/087,190	Applicant(s) CHALLITA-EID ET AL.	
	Examiner David J. Blanchard	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83 and 111-115 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83 and 111-115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/21/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-82 and 84-110 are cancelled.
Claim 83 has been amended.
Claims 111-115 have been added.
2. Claims 83 and 111-115 are under consideration to the extent that the transcript variant encodes the protein of SEQ ID NO:5, i.e., applicants' elected species.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. This Office Action contains New Grounds of Rejections.

Information Disclosure Statement

5. The Information Disclosure Statements (IDS) filed 21 December 2007 has been fully considered. A signed and initialed copy of the IDS is included with this Office Action. Applicants' remarks and request for consideration of references 3 and 4 are acknowledged. As stated in the previous Office Action, references 3 and 4 were fully considered by the examiner. The fact that the references were lined through on the 1449 mailed 1/14/08 merely indicated that the references would not be printed on the face of a patent issuing from the present application. In view of Applicants' remarks and request, references 3 and 4 on the IDS are not lined through on the IDS included with this Office Action.

Withdrawn Rejections

6. The rejection of claim 83 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation "which variant is immunoreactive with at least one antibody that specifically binds the amino acid sequence of SEQ ID NO:2" is withdrawn in view of the amendments to the claim.

Rejections Maintained and New Grounds of Rejections

7. The rejection of claim 83 and now applied to newly added claims 111-115 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated 121P1F1 transcript or transcripts that encode the protein of SEQ ID NO:2, does not reasonably provide enablement for: (i) any isolated 121P1F1 transcript variant that encodes a protein comprising at least one amino acid substitution, addition or deletion relative to SEQ ID NO:2 *or the transcript variant of SEQ ID NO:5* is maintained.

The response filed 7/14/2008 states that the claims are narrowly drawn to a polynucleotide that encodes a protein having the sequence of SEQ ID NO:5, which protein is immunoreactive with an antibody that specifically binds to amino acids 1-92 of SEQ ID NO:3. Applicant states that it would not require undue experimentation to prepare a polynucleotide encoding a protein having a sequence of SEQ ID NO:5 nor to prepare a polynucleotide containing the sequence of SEQ ID NO:4. Applicant states that the specification provides at least one working example involving the claimed polynucleotides, which are used in Northern Blot analysis of normal tissues and cancerous tissues and one of skill in the art can use this example to devise other assays relating to cancer using other polynucleotide sequences of the claimed subject matter. At pg. 7 of the response, Applicant points to the specification as disclosing the expression of 121P1F1 in cancer. Since nucleic acid residues 1-867 of SEQ ID NO:2 (121P1F1) are identical to nucleic acid residues 1-358 and 518-1028 of SEQ ID NO:4 (121P1F1 transcript variant), Applicant asserts that detection of SEQ ID NO:2 by RT-PCR and Northern blotting also detects SEQ ID NO:4, which encodes SEQ ID NO:5. Applicant also argues that the polynucleotide sequence encoding SEQ ID NO:5 is a naturally occurring transcript variant of the nucleotide sequence comprising SEQ ID NO:1 that encodes SEQ ID NO:2 and the specification teaches expression systems and host cells for producing a 121P1F1 polypeptide and antibodies to the polypeptide. Applicant states that a polyclonal antibody to 121P1F1 showed strong reactivity to variants of 121P1F1 in a number of cancer cell lines. Applicant states that based on the expression profile of 121P1F1 in cancer, the splice variants of 121P1F1 that are

structurally and/or functionally similar to 121P1F1 can also serve as tumor-associated markers/antigens. Applicant refers to the specification as providing sufficient guidance in the specification on how to conduct tests related to detection of cancer markers using the claimed polynucleotides. Applicant concludes that since SEQ ID NO:3 was shown to be overexpressed in cancerous tissue, that antibodies which detect amino acids 1-92 of SEQ ID NO:3 are also useful for detecting SEQ ID NO:5, which shares this region of identity. Applicants' arguments have been fully considered but are not found persuasive. With the exception of newly added claim 111, the claims are broadly drawn to various nucleic acid sequences that encode the protein of SEQ ID NO:5 as well as a broader genus of nucleic acids which encode "a protein of SEQ ID NO:5", which is inclusive to a variety of protein fragments and variants of SEQ ID NO:5 (126 amino acids in length), since a fragment of 100 amino acids of SEQ ID NO:5 is merely one interpretation of "a protein of SEQ ID NO:5". Even if the claims were narrowly drawn to the nucleic acid of SEQ ID NO:4 which encodes SEQ ID NO:5 (i.e., claim 111), the claims would still be nonenabled. Applicant is again reminded that the enablement of the 121P1F1 protein of SEQ ID NO:3 is based on the disclosure that SEQ ID NO:3 is encoded by the nucleotide sequence of SEQ ID NO:2 which is shown to be highly expressed in prostate cancer. Thus, while applicant has enabled the 121P1F1 nucleic acid and protein (e.g., SEQ ID Nos:1 and 2 of US Patents 7,309,585 and 6,924,358), Applicant has not disclosed an activity or biological function of the 121P1F1 protein of SEQ ID NO:2, or any variants thereof. Applicant has not taught how to make and use a transcript variant that encodes a protein of SEQ ID NO:5 or encodes the protein of SEQ ID NO:5 because the instant application does not disclose the genus of transcript variants encoding SEQ ID NO:5 which share the function(s) and/or characteristic(s) of the 121P1F1 protein of SEQ ID NO:3, e.g., highly expressed in prostate cancer. The specification does not provide sufficient guidance as to which isolated 121P1F1-related protein (e.g., SEQ ID NO:5) would share the same function as the 121P1F1 protein of SEQ ID NO:3, if known. Neither does the specification provide any working examples of any 121P1F1-related protein (e.g., SEQ ID NO:5) that have the same functional activities or characteristics, i.e., highly expressed in prostate cancer as the 121P1F1

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protein of SEQ ID NO:3. The examiner agrees that one skilled in the art could make a protein having a sequence of SEQ ID NO:5 and could make a polynucleotide containing the sequence of SEQ ID NO:4, however, the issue remains that one skilled in the art would not know how to use a protein of SEQ ID NO:5 or how to use the 121P1F1 transcript variant of SEQ ID NO:4. Applicants' arguments that one skilled in the art could use the disclosed working example directed to 121P1F1 to devise other assays relating to cancer using other polynucleotide sequences of the claimed subject matter, i.e., 121P1F1 transcript variants, and applicants' arguments that one skilled in the art could use the disclosed expression systems and host cells to produce the claimed 121P1F1 variants as well as methods to generate antibodies against the 121P1F1 variant does not provide any guidance or direction to assist those skilled in the art how to use the presently claimed 121P1F1 transcript variant of SEQ ID NO:4 or the encoded polypeptide of SEQ ID NO:5 or variants thereof, i.e., "a protein of SEQ ID NO:5". In short, the instant application describes methods for producing 121P1F1 transcript variants encoding a protein of SEQ ID NO:5 and methods for producing the 121P1F1 variant of SEQ ID NO:5 as well as generating antibodies thereto as well as assays to determine whether the claimed 121P1F1 are differentially expressed in certain cancers, however, these descriptions, without more precise guidelines, amount to little more than "a starting point, a direction for further research." *Genentech*, 108 F.3d at 1366. See also *Calgene*, 188 F.3d at 1374 ("the teachings set forth in the specification provide no more than a 'plan' or 'invitation' for those of skill in the art to experiment practicing [the claimed invention]; they do not provide sufficient guidance or specificity as to how to execute that plan"); *National Recovery Technologies*, 166 F.3d at 1198 (stating that patent-in-suit "recognizes a specific need... and suggests a theoretical answer to that need. It provides a starting point from which one of skill in the art can perform further research in order to practice the claimed invention, but this is not adequate to constitute enablement"). The instant specification does not describe the claimed invention in terms that will "enable any person skilled in the art... to make and use" the invention commensurate in scope with the claims. At most, the specification will enable a person of ordinary skill in the art to attempt to discover how to practice the claimed invention.

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In essence, Applicants' disclosure invites the skilled artisan to experiment to determine for themselves how to use a 121P1F1 transcript variant that encodes a protein of SEQ ID NO:5 and how to use the protein of SEQ ID NO:5. There is no basis or objective evidence that one skilled in the art would reasonably know how to use the 121P1F1 transcript variant of SEQ ID NO:4 as a cancer diagnostic, nor how to use "a protein of SEQ ID NO:5" or the protein of SEQ ID NO:5 as a cancer diagnostic and the instant application does not disclose an activity or biological function of the 121P1F1 protein of SEQ ID NO:2, or any variants thereof.

In view of the lack of the predictability of the art to which the invention pertains as evidenced by Bost et al and Bendayan M, Altwood et al, Skolnick et al, Metzler et al, Lerner R. A., Mikayama et al, Burgess et al, Lazar et al and Ngo et al, all of record), the lack of guidance and direction provided by applicant, and the absence of working examples, undue experimentation would be required to practice the claimed transcript variants of SEQ ID NO:4 that encode a protein of SEQ ID NO:5 with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed transcript variants and absent working examples providing evidence which is reasonably predictive that the claimed transcript variants of SEQ ID NO:4 that encode a protein of SEQ ID NO:5 have the same functional activities or characteristics of the disclosed 121P1F1 nucleic acid of SEQ ID NO:2 and the encoded protein of SEQ ID NO:3, commensurate in scope with the claimed invention.

8. Claims 83 and 111-115 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The response filed 7/14/2008 has introduced NEW MATTER into the claims. Presently amended claim 83 recites an isolated nucleic acid sequence that encodes a

protein of SEQ ID NO:5, where the protein is immunoreactive with at least one antibody that specifically binds to amino acid residues 1-92 of SEQ ID NO:3. Newly added claims 111-115 recite wherein the nucleic acid is SEQ ID NO:4, viral vectors and isolated host cells, and a process for producing a protein having the sequence of SEQ ID NO:5. The response did not point out where support for the limitation “where the protein is immunoreactive with at least one antibody that specifically binds to amino acid residues 1-92 of SEQ ID NO:3” as presently amended in claim 83, could be found in the originally filed disclosure. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 (“Applicant should therefore specifically point out the support for any amendments made to the disclosure.”). Support for the limitation of an antibody that specifically binds to amino acid residues 1-92 of SEQ ID NO:3 could not be found in the as filed specification or claims.

As currently presented, claims 83 and 111-115 now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in currently presented claims 83 and 111-115, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in present amended and newly added claims in the specification or claims, as filed, or remove these limitations from the claims in response to this Office Action.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643